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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference TRCA-004WO	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/US04/41308	International filing date (day/month/year) 10 December 2004 (10.12.2004)	Priority date (day/month/year) 11 December 2003 (11.12.2003)	
International Patent Classification (IPC) or national classification and IPC IPC: A61K 38/00(2006.01);C07K 14/00(2006.01) USPC: 514/2;530/350			
Applicant TERCICA, INC.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 27 May 2005 (27.05.2005)		Date of completion of this report 14 April 2006 (14.04.2006)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Laura Goddard <i>J. Roberts for</i> Telephone No. 571-272-8788	

Form PCT/IPEA/409 (cover sheet)(April 2005)

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Box No. I Basis of the report1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:
- pages 1-53 as originally filed/furnished
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☒ the claims:
- pages 54-56 as originally filed/furnished
- pages* NONE as amended (together with any statement) under Article 19
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☒ the drawings:
- pages 111 as originally filed/furnished
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 11-15

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 11-15 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 11-15 are improper multiple dependent claims.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☐ no international search report has been established for said claims Nos. _____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-10, 16-25</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>17</u>	YES
	Claims <u>1-10, 16, 18-25</u>	NO
Industrial Applicability (IA)	Claims <u>1-10, 16-25</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V. 2. Citations and Explanations:

Claims 1-5, 9, and 18 lack an inventive step under PCT Article 33(3) as being obvious over Fuh et al (J Biological Chemistry, 1995, 270:13133-13137) and US Patent 5,854,026 (issued 29 December 1998).

Fuh et al (p. 13133, col. 1) and US Patent 5,854,026 (col. 22, lines 56-67) teach the treatment of breast cancer with human prolactin (hPRL) receptor antagonists such as human growth hormone (hGH) variants. Fuh et al teach that zinc increases the affinity of hGH for the hPRL receptor (abstract; p. 13134, col. 2). Fuh et al teaches ZnSO₄ (p. 13134, col. 1). US Patent 5,854,026 teaches that hGH variants may inhibit the growth of cells expressing prolactin receptors, wherein the variant is an antagonist that binds to the prolactin receptor (col. 22, lines 62-67).

Claims 6 and 10 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Rosoff et al (The Prostate, 1982, 3:615-622).

Rosoff et al teach that there are prolactin receptors in the prostate (p. 615).

Claims 1-3, 8, and 25 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the preceding paragraphs and further in view of Cunningham et al (Science, 1990, 250:1709-1712).

Cunningham et al teach that zinc is required for tight binding of hGH to the hPRL receptor (p. 1709, col. 1) and teach the administration of different concentrations of zinc with hGH (Fig. 2). Cunningham et al teach a composition comprising zinc and hGH

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Supplemental Box

to optimize the hormone receptor complex (p. 1709, col. 2).

Claim 16 lacks an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the preceding paragraphs and further in view of Chen et al (International J Oncology, 2002, 20:813-818).

Chen et al teach the administration of a hPRL receptor antagonist in slow-releasing pellets to inhibit breast cancer cell growth in vivo (p. 813, col. 2).

Claims 19, 21, 22, and 24 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the preceding paragraphs and further in view of Mah et al (Semin Reprod Med, 2002, 20:365-374).

Mah et al teach that dopamine agonist therapy is the treatment of choice in most cases of hyperprolactinemia, with surgery being reserved for patients unresponsive to or intolerant of the medical therapy (p. 371, col. 2).

Claims 7 and 23 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the preceding paragraphs and further in view of Xu et al (Cancer Research, 2001, 61:6098-6104).

Xu et al teach antiandrogen or prolactin receptor antagonist therapy to combat cell proliferation disease such as hyperplasia (abstract; p. 6098, col. 1 and 2).

Claim 20 lacks an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of US Patent 5,677,171 (issued 14 October 1997).

US Patent 5,677,171 teaches the treatment of patients with a Her-2 receptor antagonist (col. 11).

Claim 17 meet the criteria set out in PCT Article 33(2)-(3) because the prior art does not teach or fairly suggest the claimed invention.

Claims 1-10 and 16-25 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.